

### **REMARKS**

This is in response to the non-final Office Action dated February 7, 2008.

Independent claim 1 and its dependent claims 2, 3, 4, and 10, independent claim 7, independent claim 11 and independent claim 14, are currently pending and at issue. Claim 1 is currently amended. Claim 6 is cancelled. Claims 8 and 9 were previously cancelled and claims 5, 12, 13 and 15 were previously withdrawn.

#### **Claim Rejection – 35 U.S.C. § 102(a)**

The Examiner has rejected claims 1-7 and 10-15 under 35 U.S.C. § 102(a) as being unpatentable over Zemel et al., FASEB Journal, 14(9), 1132-8 (June 2000). Applicants respectfully traverse.

In view of the attached inventor Declaration under 37 C.F.R. § 1.132, submitted in a related case, it is respectfully submitted that Zemel et al., is not prior art to the invention and that the publication disclosure was derived from the work of the inventors.

This application is a continuation of Application No. 10/066,057, filed on January 31, 2002, which is a divisional of Application No. 09/654,357 ("the '357 application"), filed on September 1, 2000, now U.S. Patent 6,384,087 ("the '087" patent). As such, the present claims are entitled to a priority date of September 1, 2000.

As set forth in the attached Declaration, the Zemel et al., article is not prior art and is based on the inventors' own work. Applicants respectfully request that the rejection based on the Zemel et al., article be withdrawn. See MPEP §§ 715.01(c) and 716.10.

#### **Claim Rejection – 35 U.S.C. § 112, First Paragraph**

The Examiner has rejected claims 1-6 under 35 U.S.C. § 112, first paragraph because the specification, while being enabling for treating health problems, does not reasonably provide enablement for avoiding health problems. The Examiner argues that "the method would appear to encompass a method of preventing health problems[.]" and that "there is no indication that the claimed method can prevent health problems due to obesity." Applicants respectfully traverse.

“The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” MPEP § 2164.01 (quoting United States v. Teletronics, Inc., 857 F.2d 778, 785 (Fed. Cir. 1988)). The specification enables a person of skill in the art to use the invention in such a way as to avoid health problems in a subject, and to do so without undue experimentation. Avoidance of health problems is discussed in the specification, for example, in paragraph [0002], which states that “[e]xcess body weight and / or an excess of body fat relative to lean body mass has been associated with a wide range of health problems including coronary artery disease, stroke, and diabetes.” The specification also describes other increased health risks in obese patients, including osteoarthritis, ligament injuries, perineal dermatitis, diabetes mellitus, cardiomyopathy, and urologic syndrome, as demonstrated in animal studies. See, e.g., paragraph [0003]. A person of skill in the art would be able to use the invention so as to avoid such health problems – i.e., by practicing the invention as claimed, which will “induce weight loss, reduce weight gain, and / or increase the metabolic consumption of adipose tissue in the individual” and thus reduce obesity and its adverse effects, and therefore avoid the health problems associated with excess body weight / obesity.

In view of the foregoing, Applicants respectfully request that the rejections be withdrawn.

#### **Claim Rejection – 35 U.S.C. § 112, First Paragraph**

The Examiner has rejected claims 1-7 and 10-15 under 35 U.S.C. § 112, first paragraph for failure to comply with the written description requirement. Applicants respectfully traverse because the specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention at the time the application was filed. MPEP § 2163.

The Examiner argues that the claim amendments reciting “at least about 773 mg per day” and “at least about 57 servings of dairy per month” introduce new matter into the claims when compared with Table 4 on page 18 of the specification. According to the Examiner, “[b]ecause the limitation of ‘at least about’ with respect to both 773 and 57 provides for variation (e.g., 10% of 773 or 57) that is greater than that provided for in Table 4,” the Examiner contends that these claim elements introduce new matter.

As an initial matter, Applicants disagree with the Examiner's contention that the phrase "at least about" provides for variation of about 10% from the recited values, a statement for which the Examiner provides no authority.

Support for this element is provided, for example, by the data in Table 4. The Examiner apparently overlooks the clear fact that each value cited by the Examiner represents a mean, and the variability in the data both within and across the four data quartiles supports the use of the term "at least about." For example, Table 4 discloses that, for the third quartile of calcium and dairy consumption, the mean daily intake of calcium is 773 mg calcium per day, and the standard error of the mean (SEM) is  $\pm 28$ . The SEM is a measure of the variability of the data within a given range. Here, an SEM of plus or minus 28 means that the actual mean intake is probably within plus or minus 28 of the stated mean of 773 (i.e., about 4%). See [http://www.graphpad.com/help/prism5/prism5help.html?stat\\_standard\\_deviation\\_and\\_standard.htm](http://www.graphpad.com/help/prism5/prism5help.html?stat_standard_deviation_and_standard.htm) (visited January 16, 2008). Table 4 also discloses that the mean number of dairy servings consumed per month for this quartile is 57.2, with an SEM of  $\pm 1.0$ . These ranges around the mean provide written description support for the term "at least about."

Likewise, for the fourth quartile of calcium and dairy consumption, Table 4 discloses that the mean daily intake of calcium is 1346 mg calcium per day, and the SEM is  $\pm 113$ . Table 4 also discloses that the mean number of dairy servings consumed per month for this quartile is 102.8, with an SEM of  $\pm 2.8$ . These ranges around the means provides written description support for the term "at least about."

In view of the foregoing, Table 4 provides ample written description for the claim terms "at least about 773 mg calcium per day" and "at least about 57 servings of dairy per month," such that one skilled in the art would reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed.

In addition, the specification provides ample support for the claim terms at issue. For example, paragraph 34 states that "a therapeutically effective amount of dietary calcium is provided to an individual," and that "a therapeutically effective amount is an amount of calcium sufficient to induce weight loss." Paragraph 9 states that "the obesity-control benefits of the subject invention are achieved by providing a diet high in calcium." Paragraph 12 states that "[t]he instant invention

also provides methods of attenuating weight gain in children by increasing the amounts of dietary calcium consumed by the children.” Paragraph 40 discusses “recommendations regarding increases in the amount of calcium consumed by the individual” when warranted by a comparison of “the amount of calcium consumed with that found to optimize or induce weight loss.” Accordingly, the specification provides ample support for these exemplary optimal and therapeutically effective amounts of “at least about 773 mg per day” and “at least about 57 servings of dairy per month.”

Accordingly, Applicants request that the rejection based on § 112 first paragraph be withdrawn.

#### **Claim Objection – 37 C.F.R. § 1.75(c)**

The Examiner has objected to claim 6 under 37 C.F.R. § 1.75(c) as being of improper dependent form. The Examiner argues that “claim 6, claiming a ‘human,’ does not further limit claim 1, wherein claim 1 limits the individual to ‘a woman.’”

Applicants respectfully traverse. The two claims are not identical. They use different terms that are susceptible to different interpretations and therefore different scope upon claim construction. Applicants therefore respectfully request that this objection be withdrawn. Further, the objection, if maintained, can be resolved upon disposition of the Request for Withdrawal of the Notice of Withdrawal from Issue (e.g., by disclaimer or examiner amendment).

#### **Conclusion**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1-4, 6, 7, 10, 11 and 14 and that the application be passed to issue. If the Examiner believes, for any reason, that

personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

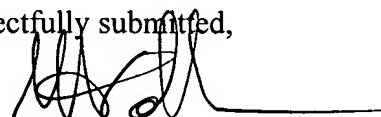
In view of the above, applicant believes the pending application is in condition for allowance.

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR §1.17, including extension of time fees pursuant to 37 CFR §1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

Dated: 3/28/08

DC2/931725

Respectfully submitted,

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